FEB 8 2007

510(k) Number: K062753

# 510(k) SUMMARY
## (As Required by 21 CFR 807. 92)

| | |
|---|---|
| **Submitted by:** | Fernando Lavoi<br>President<br>SURGIMED, INC<br>1303 NW 78 Avenue<br>Miami, Florida 33126<br>Tel: 305 594-1121<br>Fax: 305 594-4343 |
| **Date of Summary:** | March 15,, 2006 |
| **Device Name:** | FORSURE™ Disposable Syringes with Needle<br>FORSURE™ Disposable Syringes for Insulin with Needle (1ml/U-100 30G x ½") |
| **Common Name:** | Hypodermic Syringe with Needle |
| **Classification Name:** | Piston Syringe |
| **Class:** | 2 |
| **Product Code:** | FMF |
| **Regulation Number:** | 21 CFR 880. 5860 |
| **Predicative Device:** | Becton Dickinson® Disposable Syringe (K980580) |
| **Modifications:** | There are no modifications to the device design that affect safety and effectiveness for its intended use. |
| **Device Description** | The FORSURE™ Disposable Syringes with Needle are Single Use, Sterile, Non-Pyrogenic devices used to inject fluids into or withdraw fluids from the body. |

K060772

| | |
|---|---|
| **Intended Use:** | To inject fluids into or withdraw fluids from the body. |
| **Technological Characteristics** | The FORSURE™ Disposable Syringes with Needle have the same technological characteristics as the legally marketed Becton Dickinson Syringes. |
| **Testing:** | The FORSURE™ Disposable Syringes with Needle have been subjected to performance and safety testing to verify mechanical properties and functioning, as well as biocompatibility and sterility, using FDA recognized Standards, where applicable |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fernando Lavoi
President
Surgimed, Incorporated
1303 NW 78 Avenue
Miami, Florida 33126

FEB 8 2007

Re: K062753
Trade/Device Name: FORSURE™ Disposable Syringes with Needle; FORSURE™ Disposable Insulin Syringes (1ml/U-100 30G x ½")
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: January 11, 2007
Received: January 12, 2007

Dear Mr. Lavoi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

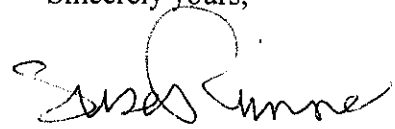
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

**510(k) Number** K062753 **(To be assigned by FDA)**

**Device Name: FORSURE™ Disposable Syringes with Needle**

**INDICATIONS FOR USE:** To inject fluids into or withdraw fluids from the body.

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED**

---

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** X **OR** **Over- The Counter Use:** ____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K062753

# INDICATIONS FOR USE STATEMENT

**510(k) Number** K062753 **(To be assigned by FDA)**

**Device Name: FORSURE™ Disposable Insulin Syringes (1ml/U-100 30G x ½")**

**INDICATIONS FOR USE**: For Injection of Insulin U-100 only.

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED**

---

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use**____ **OR** **Over- The Counter Use:** X

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K962753